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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,057	10/05/2000	Edwin W. Ades	14114.0381U2.	7894

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,057	ADES ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 13-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5-021

DETAILED ACTION

1. Applicants' Response to Notice of Non-Compliant Amendment, received 9February2005, is acknowledged. Claims 13-15 and 22 have been amended. New Claims 25-29 have been added.

2. Applicants' Revocation and Substitute Power of Attorney, received 27December2004, is acknowledgd.

3. Applicants' Response to Office Action, received 18october2004, is acknowledged.

4. Claims 13-29 are pending and under consideration.

Rejections Withdrawn

5. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claim.

6. The rejection of claims 14-19 under 35 U.S.C. 112, second paragraph, indefiniteness, for the two descriptors "percent purity" and "substantially pure" is withdrawn in light of the amendment of claim 14.

Rejections Maintained

7. The rejection of claims 20-24 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccination with any/all preparations of lipidated PsaA, is maintained for reasons of record.

Applicants argue that the specification enables a method applicable to the claimed PsaA and describes numerous art-recognized administration methods, e.g., nasal or respiratory administration.

The examiner agrees that the specification does discuss various means of administration of the claimed PsaA. However, as stated in the original rejection, the examples provided by

applicants do not specify the route of administration. Thus, the examiner can not make an accurate assessment for either the presence or lack of support for nasal administration.

Applicants argue that the third example of *in vivo* studies shows effective passive immunization of 60% of mice receiving seera raised H5-produced lipidate PsaA and admit that lipidated PsaA produced in Sf9 cells was not effective (or was injurious). Thus, the example guides the skilled person to prefer H5 cell-produced lipidated PsaA over Sf9 cell-produced lipidated PsaA for raising antibodies for passive immunization.

The examiner has considered applicants argument, and points out that the instant claims are not restricted to H5-produced lipidate PsaA, but are drawn to any/all preparations of PsaA, thus including Sf9 cells. As admitted by applicants, Sf9 cell produced lipidated PsaA was not effective (or was injurious). Thus, one cell line is effection, one cell line is injurious. However, the claims are drawn to a genus, i.e., any cell line. The information concerning the two cell lines utilized indicate that one does not have a reasonable expectation of success for any/all PsaA preparations produced by a cell line other than H5.

Therefore, the claims remain rejected.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method wherein lipidated PsaA is recombinantly produced in "a high five cell".

The instant specification lists a supposed cell as "High Five" or H5, but does not refer to "high five". Thus, is is unclear if the cell in the claims is the same as that of the specification.

In addition, it is unclear what is the identity of the "High Five" or H5 in the specifcation because the term is not defined even thought there are other cell lines designated by terms and ATCC numbers.

10. Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a recombinant lipidated PsaA protein encoded by a hybrid nucleic acid molecule comprising a first nucleic acid sequence encoding a signal sequence of a lipoprotein other than PsaA and a second nucleic acid sequence endocing a mature PsaA protein, or immunogenic fragment thereof.....

It is unclear if the immunogenic fragment is of the lipoprotein other than PsaA, the mature PsaA, or the hybrid protein.

Claims 26 and 27 depend from 25, but do not clarify the issue.

11. Newly amended claims 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants argument concerning the rejection of claims 14-19, *supra*, states that the combination of percent purity and "substantially free" means that the recited components are substantially excluded from the <20% contaiminants. Thus, the overall contamination may be

up to <20%, but the amount of protein and lipopolysaccharide contamination within the contaminant fraction must be insubstantial.

While the amendment of claim 14 removes the conflict concerning the issue of percent purity and "substantially free", applicants argument concerning their definition of "substantially free", makes claims 13-19 indefinite. It is unclear what is "substantially free" because applicants define "substantially free" utilizing the indefinite term "insubstantial". Thus, it is unclear what are the metes and bounds of "substantially free".

Claims 15-19 now depend from claim 13 which states that the preparation is "substantially free" from lipopolysaccharides and contaminant proteins. Claim 15 recites "the recombinantly produced, lipidated PsaA protein of claim 13 wherein said protein has a purity of at least 95%. Thus, claims 13 is drawn to a "substantially free" product, and claims 15-19 are drawn to a protein which "has a purity of at least 95%" and is "substantially free" from lipopolysaccharides and contaminant proteins.

Conclusion

12. Claims 14-29 are finally rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

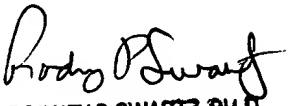
will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

May 16, 2005